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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|-----------------------|---------------------|------------------|
| 10/804,583 | 03/18/2004 | Edgardo Costa Maianti | DID1046US | 7264 |
| 9561 | 7590 | 01/07/2010 | EXAMINER | |
| POPOVICH, WILES & O'CONNELL, PA | | | CHAPMAN, GINGER T | |
| 8519 EAGLE POINT BLVD | | | | |
| Suite 180 | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/804,583 | MAIANTI ET AL. | |
| | Examiner | Art Unit | |
| | Ginger T. Chapman | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 November 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3 and 7 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3 and 7 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 06 January 2009 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/02/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 November 2009 has been entered.

Status of the Claims

2. Claims 1-3 and 7 are pending in the application, claim 1 is amended.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Raible (US 5,770,149).

5. With respect to claim 1, as best depicted in Figures 1-3, Raible discloses an integrated device 10 (Figure 1) (col. 1, lines 45-49 and lines 59-60) Figures 1-3, for oxygenating and filtering blood flowing through an extracorporeal circuit comprising:

6. a bubble trap 30, at column 6, lines 19-27 teaching that the cavity 30 comprises bubble outlet port 31 and associated cap 33 member at the top of the cavity 30 to permit the air bubbles

collecting at the top of cavity 30 to be vented or aspirated and removed through the air bubble port outlet 31 of chamber 30, therefore the examiner is considering the cavity 30 to be a bubble trap since it performs the function of trapping, i.e. collecting and venting the trapped bubbles; (the examiner notes that Raible also discloses the bottom portion of the cavity 30 below the bubble outlet port 31 may also house the impeller 40 of the pump 14), an inlet 28 for receiving venous blood and an outlet 52 for supplying venous blood, teaching at col. 6, lines 34-38 that the bottom portion of the cavity 30 is in fluid communication with an annular blood outflow space 52, i.e. an “outlet” through which venous blood may exit the cavity 30, therefore the examiner is considering the blood outflow port 52 at the bottom of cavity 30 to be “an outlet for supplying venous blood” because the outflow port supplies venous blood which flows from cavity 30 down into the next portion downstream of the cavity 30 of the device;

7. a blood pump 14, at column 6, lines 44-63 and Figures 2 and 3 teaching pump 14 motor drive and the pump comprises elements 48, 46, 44, 42, 40, 38; the impeller 48 and impeller assembly 38 are housed with the bottom portion of cavity 30, therefore the inlet 28 which supplies blood to cavity 30 also provides an inlet 28 to the portion 38, 40 of the pump because the pump receives venous blood via inlet 28, and an outlet 52 because the blood outflow port 52 of cavity 30 supplies venous blood flowing past the pump 14 impellers 40 down into the next portion downstream of the impellers 40, and the blood outflow port i.e. outlet 52 is positioned at a top of the blood pump 14 because the pump 14 is positioned below the outlet 52 and thus the outlet is positioned at a top of the blood pump;

8. a heat exchanger 54 (col. 7, line 7) having a blood inlet 50 (col. 7, lines 57-58: teaching that blood flows out of outlet 52 into heat exchanger 54 cavity 50, therefore the examiner is

considering the inlet port of heat exchanger cavity 50 where the blood flows from outlet 52 into cavity 50 to be the inlet, said inlet 50 connected 52 to receive venous blood from outlet 52 of the pump 38, see column 7, lines 53-60, teaching blood flowing from inlet 28 into bubble trap 30 past impellers 38 of the pump 14 through outflow 52 into heat exchange cavity 50 including heat exchangers 54) and a blood outlet 70 (col. 8, lines 1-5 and col. 7, lines 61-67);

9. The examiner notes that Raible discloses the circuit in terms of blood flowing into and out of the cavities without expressly disclosing that each cavity necessarily and inevitably must comprise inlets and outlet through which blood must flow into and out of the cavities; therefore the examiner is considering the inlet to each cavity and the outlet from each cavity of Raible as comprising inlets and outlets, although not explicitly labeled with reference characters in the disclosure of Raible.

10. an oxygenator 74 (col. 8, line 13) having an inlet 72 (col. 8, lines 1-13) connected to receive venous blood from the outlet 50 of the heat exchanger 54 and an outlet 72 for supplying oxygenated blood;

11. an arterial blood filter having an inlet connected to receive oxygenated blood from the outlet of the oxygenator and an outlet for supplying filtered oxygenated blood (Figures 9a, 9b; column 12, lines 55-57; lines 66 to column 13, lines 1-5); and

12. a monolithic housing 12 Figs. 1 and 2 (col. 5, line 22) including first portion 30 (figure 3) positioned at the top of the monolithic housing (fig. 1) for defining a bubble trap 30, 31, a second portion 14 positioned at the bottom 13 of the monolithic housing 12 for defining the blood pump 14 (see Figure 2: 16, 17, 48 and Figure 3: elements 48, 46, 44, 42, 40, 38), a third portion 50 for defining the heat exchanger 54, a fourth portion 70, 72 for defining the arterial blood filter,

wherein the integrated device does not comprise a venous reservoir (column 12, lines 7-23, Figure 8: teaching a separate embodiment and where an optional venous reservoir may or may not be included depending on the intended use of the device determined by a treating physician on a case by case basis, for example, for surgical drainage one may select to include an optional reservoir or can select to omit it).

13. With respect to claim 2, Raible discloses the blood pump 14 comprises a centrifugal pump (c. 6, line 45).

14. With respect to claim 7, Raible teaches monolithic housing 12 is configured such that blood flowing through the extracorporeal circuit is directed through the bubble trap (outlet 33, 31 of chamber 30) before the blood enters the blood pump (col. 6, lines 22-27).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17.

18. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raible in view of Israelev (US 5,924,848).

19. With respect to claim 3, Raible discloses the claimed invention except for the horizontal axis. Raible discloses the centrifugal pump has an axis and is positioned within the monolithic device such that the axis of the pump is vertical (c. 10, l. 430, thus providing motivation for a centrifugal pump having an axis.

20. Israelev teaches a centrifugal pump for extracorporeal blood circuit in which the axis of the pump may be either horizontal or vertical (c. 3, ll. 58-59); thus teaching that either horizontal or vertical rotation of axis is suitable for use in an extracorporeal device and thus appears to be an obvious modification within the skill of one of ordinary skill in the art to select an orientation depending on the desired configuration of the components comprising the device.

21. When the axis of rotation of the pump is horizontal, a pump outlet would perform as though the outlet is on the top, when the axis is vertical, the outlet would perform as though it were tangential. Therefore the substantially identical pump can provide either axis of rotation and it would be a matter for the designer to select one of these two axes of rotation depending on how the designer wishes to configure the device and thus is an obvious modification.

22. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide either a horizontal or vertical axis since both perform the substantially identical function in the substantially identical manner and it would thus be a matter of obvious design choice of the designer to select one of these known orientations as taught by Israelev in the circuit of Raible since Israelev states, at c. 3, ll. 54-60 that the benefit of using

such a centrifugal pump is that it remains stable when the direction of the pump's axis of rotation is changed when the position of the device's housing is changed to allow for flexibility in positioning the pump.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ghelli US 6,723,283 B2, Figure 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
12/17/09

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/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772